

REMARKS

Applicants acknowledge receipt of the Office Action mailed June 23, 2005.

Before entry of this Reply, claims 25-38 and 58-62 were pending in this application. After entry of this Reply, claims 25-38 and 58-62 remain pending in this application. Of these claims, claims 25 and 33 are independent.

In the Office Action, the Examiner (1) rejected claims 33-36 under 35 U.S.C. § 103(a) as being unpatentable over *Castellano et al.* (U.S. Patent No. 5,728,074) in view of *Allen et al.*¹ (U.S. Patent No. 5,837,546) and *Buse et al.* (U.S. Patent No. 6,591,125); (2) rejected claims 37 and 38 under 35 U.S.C. § 103(a) as being unpatentable over *Castellano* in view of *Buse* and *Davies et al.* (U.S. Patent No. 6,733,655); (3) rejected claim 39 as being unpatentable over *Castellano* in view of *Buse* and *Davies*, and further in view of *White et al.* (U.S. Patent No. 5,438,271); (4) objected to claims 34 and 40 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims; and (5) allowed claims 25-32.

Applicants gratefully acknowledge the Examiner's indication of allowable subject matter in claims 25-34.

In addition, Applicants gratefully acknowledge the Examiner's indication of allowable subject matter in claims 34 and 40. However, Applicants have not rewritten

¹ Applicants believe that the Examiner intended to reject **claims 33, 35, 36, 41-43** under 35 U.S.C. § 103(a) as being unpatentable over *Castellano et al.*, in view of *Davies et al.* (U.S. Patent No. 6,733,655) and *Buse et al.* Should the Examiner persist in issuing any rejections under a combination of these references, Applicants respectfully request that the Examiner clarify the outstanding rejection of these claims. Applicants have nonetheless attempted to be fully responsive to the Examiner's concerns in this paper in an attempt to advance prosecution.

these claims to include all of the limitations of the base claim and any intervening claims because claim 33 is patentably distinguishable over the cited prior art.

Applicants traverse the Examiner's rejections for at least the reasons discussed below.

I. §103(a) REJECTION OF CLAIMS 33-36

Claims 33, 35, 36, and 41-43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Castellano*, in view of *Davies* and *Buse*. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), each of three requirements must be met. First, the reference or references, taken alone or combined, must teach or suggest each and every element recited in the claims. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references in a manner resulting in the claimed invention. Third, a reasonable expectation of success must exist. Moreover, each of the three requirements must "be found in the prior art, and not be based on applicant's disclosure." See M.P.E.P. §2143, 8th ed., February 2003.

Claim 33 recites, *inter alia*:

A method of using a test strip to test a blood sample, said test strip including a sample chamber, a working electrode, a counter electrode, a pair of fill-detect electrodes, and an auto-on conductor

The Examiner admits that "*Castellano*, as modified by *Buse* and *Davies*, teaches wherein a working electrode and one of the counter electrodes are used as the pair of

fill-detect electrodes, rather than providing a separate pair of fill-detect electrodes.”

Office Action, p. 4, ll. 3-6. The Examiner further asserts that “[a]pplicants have not disclosed that providing the fill-detect electrodes separately from the working and counter electrodes solves any stated problem or is for any particular purpose.” *Id.* at p. 4, ll. 6-8.

Applicants respectfully traverse the Examiner’s assertions, and submit that the Examiner has not met the burden required to establish a prima facie case of obviousness. The Examiner asserts that Applicants have not shown that separate electrode pairs solve any stated problem or are for any particular purpose. Applicants respectfully submit that this is not Applicants’ burden until a prima facie case of obviousness has been established, but present these arguments for the Examiner’s consideration notwithstanding.

The working and counter electrodes 22 and 24 serve a function different and independent from that of fill-detect electrodes 28 and 30. A first validation voltage is applied between the working and counter electrodes 22 and 24 to determine whether a blood sample is present in the sample chamber 88. Once the current between the working and counter electrodes 22 and 24 reaches a predetermined threshold value, the meter disconnects working and counter electrodes 22 and 24 and starts a fill timer. As soon as meter 200 starts the fill timer running, meter 200 applies a second validation voltage between the fill-detect electrodes 28 and 30 and measures the current flowing therefrom to determine whether sufficient blood sample has reached fill-detect electrodes 28 and 30 and whether the sample has become mixed with the chemical constituents in reagent layer 90. *Specification*, p. 28, line 21 – p. 29, line 21. Thus, the

working and counter electrodes 22 and 24 and the fill-detect electrodes 28 and 30 separately provide indications and validations to the meter as to the status of blood glucose measurement, with both sets of electrodes being equally important in obtaining an accurate test result.

In the outstanding rejection, the Examiner has not provided a combination of references that teach or suggest each and every element recited in the claims. Second, the Examiner has provided no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references in a manner resulting in the claimed invention. Indeed, the Examiner has merely opined that the claimed combination would have been obvious to one having ordinary skill in the art without providing any evidence supporting this opinion. Lastly, the only source for the combination or its desirability is apparently Applicants' own disclosure.

Thus, for at least these reasons, the invention of claim 33 is not taught by *Castellano*, *Davies*, *Buse*, and the other art of record, whether taken alone or in combination. Accordingly, Applicants respectfully request that the rejection of claim 33 under 35 U.S.C. § 103(a) be withdrawn and the claim allowed.

Claims 34-38 and 58-62 depend from claim 33. As explained above, claim 33 is distinguished from *Castellano*, in view of *Davies* and *Buse*, whether taken alone or in combination. Accordingly, claims 34-38 and 58-62 are also distinguished from *Castellano*, *Davies*, and *Buse*, for at least the same reasons as claim 33. Applicants respectfully request that claims 34-38 and 58-62 be allowed along with independent claim 33.

II. CONCLUSION

Applicants respectfully submit that independent claims 25 and 33 are in condition for allowance. In addition, claims 26-32, 34-38, and 58-62 are in condition for allowance at least due to their dependency from claims 25 and 33, respectively.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

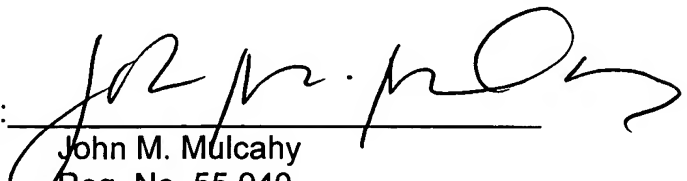
Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, L.L.P.

Dated: September 23, 2005

By: _____


John M. Mulcahy
Reg. No. 55,940